Pliant Therapeutics Announces Initiation of BEACON-IPF, a Phase 2b Clinical Trial of Bexotegrast in Idiopathic Pulmonary Fibrosis

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Follows positive data from INTEGRIS-IPF Phase 2a trial

SOUTH SAN FRANCISCO, Calif., Aug. 09, 2023 (GLOBE NEWSWIRE) -- Pliant Therapeutics, Inc. (Nasdaq: PLRX), a clinical stage biotechnology company focused on discovering and developing novel therapeutics for the treatment of fibrosis, today announced the initiation of BEACON-IPF, a Phase 2b clinical trial of bexotegrast in patients with idiopathic pulmonary fibrosis (IPF). Bexotegrast is an oral, small molecule, dual-selective inhibitor of αvβ6 and αvβ1 integrins in clinical development for the treatment of IPF and primary sclerosing cholangitis (PSC).

“IPF remains an area of great unmet need. With the start of BEACON-IPF, we are achieving an important company milestone and taking a step forward to potentially bringing this novel drug candidate to patients,” said Éric Lefebvre, M.D., Chief Medical Officer at Pliant Therapeutics. “BEACON-IPF follows the positive results from our Phase 2a INTEGRIS-IPF trial demonstrating bexotegrast was well tolerated and demonstrated encouraging preliminary patient benefits for those both on and off current background therapies. We look forward to advancing this trial to further our understanding of bexotegrast as a potential therapy in the treatment of IPF.”

BEACON-IPF is a 52-week, multinational, randomized, dose-ranging, double-blind, placebo-controlled Phase 2b trial evaluating bexotegrast at doses of 160 mg or 320 mg. The trial is planning to enroll approximately 270 patients with IPF at sites globally. The primary endpoint of BEACON-IPF is the assessment of the change from baseline in absolute forced vital capacity (FVC) mL at Week 52. Secondary endpoints include the measurement of time to disease progression (≥10% absolute decline from baseline in FVC precent predicted (FVCpp), respiratory-related hospitalization, or all-cause mortality), change from baseline in absolute FVC (mL) on or not on background therapies, change from baseline in patient reported measurements of symptoms, well-being at Week 52 and safety and tolerability.

About Idiopathic Pulmonary Fibrosis

IPF is a chronic, progressive, fibrosing lung disease of unknown cause with few treatment options and a poor prognosis. Patients experience debilitating symptoms, including shortness of breath and difficulty performing daily activities, such as walking and talking. Currently, there is no pharmacological cure for IPF, with neither of the approved two therapies demonstrating an ability to stop the progression of IPF. Therefore, there is a high unmet need for new therapeutic options to address the symptoms and modify the disease progression of this grievous illness.

About Pliant Therapeutics, Inc.

Pliant Therapeutics is a clinical stage biopharmaceutical company focused on discovering and developing novel therapies for the treatment of fibrosis. Pliant's lead product candidate, bexotegrast (PLN-74809), is an oral, small molecule, dual selective inhibitor of αvß6 and αvß1 integrins that is in development in the lead indications for the treatment of idiopathic pulmonary fibrosis, or IPF, and primary sclerosing cholangitis, or PSC. Bexotegrast has received Fast Track Designation and Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) in IPF and PSC and Orphan Drug Designation from the European Medicines Agency in IPF and PSC. Pliant is currently conducting a Phase 2a trial of bexotegrast in the PSC and has initiated BEACON-IPF, a Phase 2b trial in IPF. Pliant has also developed PLN-1474, a small molecule, selective inhibitor of the αvß1 integrin for the treatment of nonalcoholic steatohepatitis, or NASH with liver fibrosis. Pliant is initiating a Phase 1 study for its third clinical program, PLN-101095, a small molecule, dual-selective inhibitor of αvß8 and αvß1 integrins, that is being developed for the treatment of solid tumors. In addition to clinical stage programs, Pliant currently has a preclinical program targeting muscular dystrophies. For additional information, please visit: www.PliantRx.com. Follow us on social media: Twitter, LinkedIn, Facebook and YouTube.

Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "may," "will," "expect," "anticipate," "estimate," "intend," and similar expressions (as well as other words or expressions referencing future events, conditions, or circumstances) are intended to identify forward-looking statements. These statements include those regarding future development of bexotegrast and timing of future data from our clinical programs. Because such statements deal with future events and are based on our current expectations, they are subject to various risks and uncertainties and actual results, performance or achievements of Pliant Therapeutics could differ materially from those described in or implied by the statements in this press release. These forward-looking statements are subject to risks and uncertainties, including those related to the development and commercialization of our product candidates, including any delays in our ongoing or planned preclinical or clinical trials, the impact of the COVID-19 pandemic on our business, operations, clinical supply and plans, our reliance on third parties for critical aspects of our development operations, the risks inherent in the drug development process, the risks regarding the accuracy of our estimates of expenses and timing of development, our capital requirements and the need for additional financing, and our ability to obtain and maintain intellectual property protection for our product candidates. These and additional risks are discussed in the sections titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the year ended December 31, 2022, as updated by our Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, which are available on the SEC's website at www.sec.gov. Unless otherwise noted, Pliant is providing this information as of the date of this news release and does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

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